IFC International Formula Council

TESTIMONY OF MARDI K. MOUNTFORD, MPH
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BEFORE THE COMMITTEE ON GREAT LAKES AND ENVIRONMENT
MICHIGAN STATE HOUSE

REGARDING HB 4522 (SUBSTITUTE BILL)
THE "CHILDREN'S PRODUCT SAFETY ACT"

APRIL 29, 2010

My name is Mardi Mountford, and I am the Executive Vice President at the International Formula Council (IFC). The IFC is an association of manufacturers and marketers of formulated nutrition products, e.g., infant formulas and adult nutritionals, whose members are predominantly based in North America.* On behalf of the IFC, thank you for the opportunity to present testimony on House Bill 4522 (Substitute Bill).

The IFC respectfully opposes House Bill 4522, which would prohibit the manufacture, sale and distribution of infant formula stored in a container that contains BPA in the State of Michigan. The currently available scientific evidence does not justify such a prohibition. Liquid infant formula in metal cans has been found to contain trace levels of BPA; however, these levels are well below amounts that regulatory authorities consider a health risk.

House Bill 4522 would reduce the availability of infant formula products for the thousands of Michigan families who safely feed their babies infant formula, since the U.S. Food and Drug Administration (FDA) must approve any changes to infant formula packaging and few viable alternatives currently exist. Over 50% of Michigan infants, or approximately 48,000, participate in the U.S. Department of Agriculture's Special Supplemental Nutrition Program for Women, Infants and Children (WIC), and almost all of these infants receive infant formula through WIC. In all states, including Michigan, manufacturers are contractually obligated under Federal law to provide infant formulas in all forms and package types through WIC. Thus passage of this bill would require Michigan to resolve this legal inconsistency.

Additionally, if this bill passes, it would significantly impact hundreds of employees at infant formula manufacturing facilities in Michigan, and the availability of canned liquid and powder infant formula, leaving only a limited number of infant formula products available for Michigan families, including those in the WIC program.

Regulatory agencies worldwide continue to uphold the safety of food packaging containing trace levels of BPA. In January 2010, the FDA reiterated BPA is safe in all of its current uses and noted that families should not change their infant feeding practices, including the use of infant formula. FDA also agreed with the National Toxicology Program's conclusion that recent studies employing novel approaches designed to test for subtle effects have raised "some concern" about the potential effects of BPA on the brain, behavior, and prostate gland in fetuses, infants, and young children, and so is working with NTP to carry out in-depth studies over the next two years to answer key questions and clarify uncertainties about the risks of BPA. Additionally, the U.S. Department of Health and Human Services (HHS) stated in January 2010 that "BPA is not proven to harm children or adults." Authorities in Canada, Europe, Australia/New Zealand, Japan, and others have consistently stated there is no health risk associated with

* IFC members are Abbott Nutrition, Mead Johnson Nutrition, Nestlé Infant Nutrition, and Pfizer Nutrition.

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the trace amounts of BPA that potentially can be detected in infant formula. *(Statements by these agencies are listed at the end of this testimony.)*

The primary focus of the IFC and its member companies is and will always remain the health and welfare of infants and children around the world. The product we manufacture, infant formula, is the most highly regulated food in the world and continues to be the only safe, nutritious and recommended alternative to breast milk.

The infant formula industry takes all potential safety issues very seriously, and we support science-based efforts to produce infant formula products of the highest possible quality. The materials used in infant formula packaging meet all applicable regulatory standards. When new information becomes available on substances like BPA, we support bringing that information forward through the accepted process of scientific peer review, regulatory review and evaluation. We remain committed to working in collaboration with government and regulatory authorities to protect the health and safety of infants worldwide. As part of this commitment—and in response to changing customer and consumer preferences—our members stand ready to adopt suitable alternatives if feasible and if they meet or exceed the benefits of current food packaging materials.

While the scientific evidence continues to support the safety of BPA, the infant formula industry is partnering with our food packaging suppliers to minimize trace levels of BPA that may be contained in infant formula packaging. Simultaneously, we are working with the packaging industry as well as the FDA and the Canadian government to aggressively research and identify possible alternative packaging.

Each of these steps takes time. Just as packaging suppliers must work with regulators to identify, certify and make commercially available alternatives to the current containers, our industry must also go through a number of steps to ensure that any new packaging materials continue to provide at least the same level of quality and safety provided by our current packaging.

Today's infant formula packaging provides critical protection to maintain the quality of both the container and the nutrients for a given period of time (known as shelf life) that has been well established over years of testing. These protections are critical in preventing corrosion or environmental contamination, as well as ensuring nutrient stability, product quality and aesthetic features such as flavor and aroma – throughout the product's shelf life. The FDA requires that all of these factors must be accounted for before a manufacturer can utilize an alternative package. And although we would like to speed up the process, it is important to note that shelf life testing is a process that may require a number of years to fully complete.

Once a package is found to be viable, the process doesn't stop there. Commercialization of new packaging materials means infant formula manufacturers must modify their production lines in a variety of ways - exactly how those modifications may occur will depend on individual manufacturing processes. All manufacturers would have to make some form of change. Any packaging alternatives will be subject to ongoing safety and quality evaluations as required by law (i.e., the Infant Formula Act).

A ban on children's products containing BPA, as proposed by House Bill 4522, would result in a reduction in the number and forms of infant formula products available to consumers. IFC members agree with HHS and the FDA that the benefit of a stable source of good nutrition from infant formula and food outweighs the potential risk of BPA exposure. In the meantime, interested parties should allow the FDA to complete its review before any action is taken.

In summary, consistent with current scientific consensus on the safety of BPA, and to preserve Michigan parents and caregivers' infant feeding options, we urge the Committee to defer further action on House Bill 4522. If enacted, this legislation will unnecessarily restrict the choice of infant formulas currently available to Michigan infants and moms. There are well established national and international processes in place for evaluating the safety of products and substances such as BPA. We encourage the Committee to allow the scientific and regulatory review process to be completed before taking action on this bill.

Statements by regulatory agencies supporting the safety of BPA:

- In January 2010, the U.S. Food and Drug Administration reaffirmed the safety of BPA for use in all current food contact applications, and stated the benefit of a stable source of good nutrition, including infant formula and foods, outweighs the potential risk from BPA exposure.[i]
- In January 2010, the U.S. Department of Health and Human Services advised on its website "BPA is not proven to harm children or adults," and also stated the benefit of a stable source of good nutrition from infant formula and food outweighs the potential risk of BPA exposure.[ii]
- In January 2010, Food Standards Australia New Zealand (FSANZ) stated, "We have assessed the risk to infants and adults from exposure to BPA and agree with the conclusions reached by the US and European food regulators that the levels of exposure are very low and do not pose a significant health risk."[iii]
- In December 2009, Health Canada published the findings of its survey investigating storage time on potential BPA migration into canned liquid infant formula. Health Canada concluded: "The current dietary exposure to BPA through food packaging is not expected to pose a health risk to the general population, including newborns and infants." They also stated: "The nutritional benefits of baby food products far outweigh any potential risk."[iv] These conclusions are consistent with findings from earlier Health Canada surveys of powdered infant formula (July 2009) and canned liquid infant formula (August 2008).
- In August 2009, FDA reported the preliminary findings of its survey of BPA and infant formula to the FDA Science Board, which showed BPA levels to be very low, and consistent with earlier findings from the FDA and Health Canada.[v]
- In July 2008, an EFSA Panel reaffirmed its own 2006 risk assessment of BPA and its effects on humans, particularly infants and children. The Panel upheld its earlier assessment, which concluded that infants would need to consume hundreds of times the amount of BPA found in canned food to approach any safety concerns.[vi]

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[i] US Food and Drug Administration. Update on Bisphenol A (BPA) for Use in Foods: January 2010. http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm064437.htm

[ii] US Department of Health and Human Services. Bisphenol A (BPA) Information for Parents. January 2010. http://www.hhs.gov/safety/bpa/

[iii] Food Standards Australia New Zealand. Bisphenol A (BPA) and food packaging. January 2010. http://www.foodstandards.gov.au/educationalmaterial/factsheets/factsheets2010/bisphenolabpaandfood4688.cfm

[iv] Health Canada, Bureau of Chemical Safety, Food Directorate. Investigation of Storage Time on Potential Bisphenol A Migration into Canned Liquid Infant Formula Stored at Room Temperature. December 2009. http://www.hc-sc.gc.ca/fn-an/pubs/securit/summ-bpa-temp-eng.php

[v] US Food and Drug Administration. Minutes of the August 17, 2009, Meeting of the Science Board to the FDA. http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/ScienceBoardtotheFoodandDrugAdministration/UCM182851.pdf

[vi] European Food Safety Authority. Toxicokinetics of Bisphenol A: Scientific Opinion of the Panel on Food Additives, Flavourings, Processing aids and Materials in Contact with Food (AFC). *The EFSA Journal.* 2008; 759: 1-10. http://www.efsa.eu.int/cs/BlobServer/Scientific_Opinion/afc_ej759_bpa_%20toxicokinetics_op_en.pdf?ssbinary=true